OCT - 3 1997

K965226

LUNAR

313 W. BELTLINE HIGHWAY MADISON, WI 53713 (608) 274-2663

9.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

Contact Person: Kenneth D. Buroker
LUNAR Corporation
313 West Beltline Highway
Madison, WI 53713
Phone: (608) 288-6460
Fax: (608) 274-0853

Date: December 20, 1996

Device/Trade Name: EXPERT-XL Total Body Acquisition and Analysis Software

Common Name: Bone Densitometer

Classification Name: Bone Densitometer
21CFR 892.1170

Predicate Device: K88 4625B Total Body Software for Lunar DPX Series

K93 5454 Tissue Quantitation for DPX Series

9.1 DESCRIPTION OF THE DEVICE:

The EXPERT-XL Total Body Acquisition and Analysis Software is an accessory software option for estimation of Bone Mineral Density (BMD in g/cm^2), Lean Tissue Mass (g), and Fat Tissue Mass (g) for the Total Body and sub-regions.

9.2 SUMMARY OF TECHNICAL CHARACTERISTICS

Scans of the Total Body on the EXPERT-XL densitometer take approximately 3 minutes. The Total Body BMD estimations correlate highly (r=0.97) with corresponding regions estimated with the DPX series of products which already has 510(k) clearance. The Lean and Fat Tissue Mass estimations also correlate highly (r=0.95). The average short term precision (%CV) is 0.4% for BMD, 3.1 % for lean tissue mass, and 4.8% for fat tissue mass which is also comparable to that shown on the DPX series. The radiation exposure of 5 mrem is higher than that for the DPX series densitometers but remains low compared to the maximum permissible dose for the total body.

9.3 CONCLUSION

The results from the EXPERT-XL Total Body Acquisition and Analysis Software are comparable to the DPX results and demonstrate similar precision. No new safety and effectiveness questions are raised with the EXPERT-XL Total Body software accessory.

Signed

Kenneth D. Buroker
Name

Director, Regulatory Affairs
Title

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 1997

Richard B. Mazess, Ph.D.
President
Lunar Corporation
313 W. Beltine Highway
Madison, WI 53713

Re: K965226
Expert-XL Total Body Acquisition and Analysis Software
Dated: July 16, 1997
Received: July 17, 1997
Regulatory class: II
21 CFR 892.1170/Procode: 90 KPS

Dear Dr. Mazess:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 **INDICATION FOR USE FORM** Page 1 of 1

- 510(k) Number (if known) K965226
- Device Name: EXPERT-XL Total Body Acquisition and Analysis Software
- Indications for use:

EXPERT-XL® Total Body Acquisition and Analysis Software is used with the EXPERT-XL® bone densitometer system. This software acquires and estimates BMD, Lean Tissue Mass, and Fat Tissue Mass for the Total Body and sub-regions.

The use of the EXPERT-XL® Total Body Acquisition and Analysis Software is restricted to prescription use only. The operator's manual for the EXPERT-XL system contains the following statement:

> "United States Federal Law restricts this device to the sale, distribution, and use by or on the order of a physician."

The EXPERT-XL Total Body Acquisition and Analysis software requires a 3 minute exposure, with an exposure dose of 3 mrem. This software option is substantially equivalent to the DPX Total Body software and poses no new safety or efficacy concerns.

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Gloria E. Sypnier

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K965226

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CRF 801.109)

(Optional Format 1-2-96)